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08/756,018	11/25/1996	BRIAN SEED	00786/284002	2533

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 08/756,018
Filing Date: November 25, 1996
Appellant(s): SEED ET AL.

Karen L. Elbing, Ph.D.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/26/06 appealing from the Office action mailed 12/07/01.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 10, 12-14, 24, and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of the claimed "nucleic acid encoding a synthetic P-selectin ligand wherein said polypeptide contains a sialyl Le^x addition site and a tyrosine sulfation site, and wherein at least one of the sites is located at an amino acid position in said polypeptide which is different from its position in a naturally occurring P-selectin ligand." The specification discloses no limitation on the sites which might comprise either a "sialyl Le^x addition site" or a "tyrosine sulfation site". Absent any disclosed limitations, a "sialyl Le^x addition site" must be considered to be any amino acid capable of accepting either an O-linked or N-linked carbohydrate addition. Similarly, a "tyrosine sulfation site" must be considered to be any tyrosine. Thus, the claims would therefore encompass an essentially unlimited number of nucleic acids encoding an essentially unlimited number of polypeptides. The

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specification, however, discloses just a single functional example. One of skill in the art would therefore conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

Withdrawn Rejections

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner:

The rejection of Claims 10, 12-14, 24, and 25 under 35 U.S.C. 112, first paragraph, for lack of enablement has been withdrawn.

(10) Response to Argument

Appellant argues that more than a single functional example of a polypeptide encoded by the claimed nucleic acid comprising a sialyl Le^x addition site and a tyrosine sulfation site is disclosed.

While examples of polypeptides comprising some of the claimed limitations may be disclosed, just a single example of a polypeptide comprising all of the limitations of the claims is disclosed, i.e., a construct comprising SEQ ID NO:15 and SEQ ID NO:17. In particular, the PSGL-1 fragments do not meet the limitation of comprising non-naturally occurring P-selectin ligand sialyl Le^x addition and a tyrosine sulfation sites.

Appellant argues that the specification provides guidance for creating and identifying sialyl Le^x addition sites.

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Appellant additionally argues that the specification further provides several examples of tyrosine sulfation sites useful for creating synthetic P-selectin ligands. Finally, appellant argues that the positioning of the sialyl Le^x addition sites and tyrosine sulfation sites is adequately described. Appellant cites Figures 3 and 4.

It must first be noted that Appellants arguments would be more relevant to a rejection for lack of enablement. The instant rejection is for inadequate written description.

The invention of the instant claims comprises a nucleic acid encoding a polypeptide that comprises a *combination* of a sialyl Le^x addition site and a tyrosine sulfation site in a context such that the artificial construct binds P-selectin. Contrary to Appellant's assertions, the instant specification discloses only a construct comprising a combination of a SEQ ID NO:15 (the tyrosine sulfation site derived from Factor VIII) and SEQ ID NO:17 (the sialyl Le^x addition site derived from CD43) that meets the limitations of the claims. As set forth above, the other constructs disclosed in the specification comprise fragments of the naturally occurring P-selectin ligand PSGL-1 which would not meet the limitations of the claims.

The issue then is not whether or not individual sialyl Le^x addition sites and individual tyrosine sulfation sites can be created - they can. The issue is whether or not sufficient *combinations* of sialyl Le^x addition sites and tyrosine sulfation sites in a proper 3-dimensional context such that the construct is capable of binding P-selectin have been described - they have

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not. Again, as set forth above, just a single construct comprising SEQ ID NO:15 and SEQ ID NO:17 is disclosed. There is no disclosure of other sialyl Le^x addition sites or tyrosine sulfation sites, thus, obviously, no disclosure of combinations of these sites. Note that all of the claims are generic in the context of at least one of the binding sites. Claim 24 recites only a specific tyrosine sulfation site of SEQ ID NO:15 and Claim 25 recites only a specific sialyl Le^x addition site of SEQ ID NO:17. Given that the specification discloses only a functional P-selectin ligand comprising a combination of these two sites, it remains the examiner's position that even these most limited of claims, reciting just one of the required binding sites, comprise an inadequate written description of the invention of the instant claims.

(11) Related Proceeding(s) Appendix

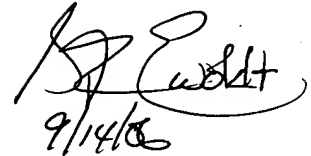
No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

G. R. Ewoldt, Ph.D.



G.R. EWOLDT, PH.D.
PRIMARY EXAMINER


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